UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

November 16, 2001

OFFICE OF
THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Note to the Reader:

The attached draft report is a draft report of the EPA Science Advisory Board (SAB). The draft is still undergoing final internal SAB review, however, in its present form, it represents the consensus position of the panel involved in the review. Once approved as final, the report will be transmitted to the EPA Administrator and will become available to the interested public as a final report.

This draft has been released for general information to members of the interested public and to EPA staff. This is consistent with the SAB policy of releasing draft materials only when the Committee involved is comfortable that the document is sufficiently complete to provide useful information to the reader. The reader should remember that this is an unapproved working draft and that the document should not be used to represent official EPA or SAB views or advice. Draft documents at this stage of the process often undergo significant revisions before the final version is approved and published.

The SAB is not soliciting comments on the advice contained herein. However, as a courtesy to the EPA Program Office which is the subject of the SAB review, we have asked them to respond to the issues listed below. Consistent with SAB policy on this matter, the SAB is not obligated to address any responses which it receives.

1. Has the Committee adequately responded to the questions posed in the Charge?
2. Are any statements or responses made in the draft unclear?
3. Are there any technical errors?

For further information or to respond to the questions above, please contact:

Mr. Samuel Rondberg, Designated Federal Officer
EPA Science Advisory Board (1400A)
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
(301) 812-2560 Fax: (410) 286-2689
E-Mail: samuelr717@aol.com

November 16, 2001

EPA-SAB-EHC/IHEC-02-XXX

Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Review of the Draft Document "Ranking Air Toxics Indoors" by the EPA Science Advisory Board

Dear Governor Whitman:

A Joint Committee of the Science Advisory Board, including Members and Consultants from the Environmental Health and Integrated Human Exposure Committees, met on July 19, 2001, to review a draft methodology for generating an order-of-magnitude, screening-level ranking of key indoor air toxics. The methodology was developed by EPA's Office of Radiation and Indoor Air (ORIA) as an outgrowth of the methodology used to select key pollutants for the National Air Toxics Program/Urban Air Toxics Strategy.

The Charge for the review , and the Joint Committee's findings, included the following issues:

a) Is the overall methodology suitable for the purposes of the ranking analysis (i.e., development of an "order-of-magnitude," screening-level ranking and selection of key air toxics indoors)?

In general, the Joint Committee finds that the proposed methodology used in the document appears to be appropriate (subject to the caveats noted below) for the purpose of providing a preliminary "order-of-magnitude," screening-level ranking of a limited selection of toxics, but the specific application is seriously flawed. As it is currently applied, the document's title is too general and implies a comprehensiveness that it does not contain. A more accurate title to the report in its current form would be "Ranking Selected Indoor Organic and Metallic Air Toxics."

Exposure data are not available for many indoor air pollutants, leading to the omission from the ranking exercise of numerous toxicants of known public health concern. These omissions result from limitations in the available data, and associated limitations in the analytical methods, sampling approaches, and/or toxicological assessments. The resultant ranking biases must be addressed by identifying the data gaps, so that better exposure data can be generated in the most important areas. Future versions of the document must make it clear to the reader that lack of data or measurements for a given agent means only that data were not available or were not considered, not that the agent is considered to be of lesser (or greater) risk.

Even with these reservations, the Joint Committee notes that even an uncertain and unstable preliminary ranking system will usually be preferable to no ranking system at all. Such a situation could lead to random choice of pollutant for study or a system that depends on the "chemical-of-the-week" syndrome or some other non-risk based set of criteria. We wish to again emphasize, however, that the results must only be used for preliminary ***relative*** ranking, i.e., to identify the "top"(highest risk) ranked or first tier chemicals of those available to be ranked, versus ones ranked in the middle or lower tiers. Although an order of magnitude ranking will work, using the results as a surrogate for absolute risk is inappropriate because of the noted uncertainties in the database. To be explicit, the results should not be used for ***absolute*** ranking.

The SAB has recently completed review of the National Air Toxics Assessment which relied heavily upon sophisticated modeling. The Joint Committee is not entirely comfortable with this document's explanation of the superiority of monitoring data to model results. Models, if properly calibrated and validated, can sometimes compensate for deficiencies in monitoring data caused by changes in exposure (e.g., the cancellation of pesticide registrations mentioned), short-term vs. long-term monitoring, etc. Given the severe limitations of existing direct monitoring data, it might be advisable to consider supplementing the approach with a "screening level" indoor fate and exposure model to draw upon other sources of information (i.e., emissions data, chemical use data, activity data, …).

b) Are the criteria used to select the monitoring studies for the analysis appropriate? Are the studies chosen for the ranking analysis suitable, and are there other studies that you

believe should be included in this analysis? Were the methods used to select and statistically analyze the data within the studies useful to the analysis?

The criteria listed in the draft document seem to be consistent with the objectives of the report. However, these criteria need to be much better defined. And, as noted above, the referenced studies do not include most of the identified indoor chemicals of public health concern. A number of indoor pollutants that have been measured repeatedly and are known to be important (e.g., carbon monoxide, radon, asbestos, fine particulates, nitrogen oxides, ozone, and compounds associated with environmental tobacco smoke) are not included in this "Ranking."

c) Is the methodology for selection of the "risk-based concentrations" (RBC) (based on that presented in the Technical Support Document for the National Air Toxics Program/Urban Air Toxics Strategy) useful in the context of this analysis?

The Joint Committee felt that the methodology for the selection of RBC was reasonable for purposes of a preliminary screening level ranking, but that the limitations of the methodology must be better explained. An appendix listing all the possible RBC for each chemical derived from each of the different data sources should be added, as well as a discussion of limitations in the toxicity studies on which the RBC were based.

d) How well have we described and addressed the adequacy, limitations, and uncertainties of the analysis, including:

1) Incomplete data on indoor concentrations and hazard/risk indices
2) Difficulties in determining the representativeness/accuracy of the "typical" levels indoors
3) The use of short-term monitoring data to represent chronic exposure periods
4) Issues related to the age of the data
5) Variations in the methods used by the various agencies to arrive at the health indices, which are the basis for the "risk-based concentrations?"

With a few exceptions, the document adequately describes and discusses the major

uncertainties of the analysis in qualitative terms. Improvements in the treatment that would enhance the utility of the document and its transparency to readers are detailed in the Joint Committee's report. Limitations and uncertainties will be more or less important depending on the decisions that will be influenced by the ranking results and the environment in which the decisions are made.

The Joint Committee also addressed some issues not specifically posed by the Charge, and advanced several recommendations, including:

a) Make the document clear as to the specific purposes for which it can be used, and by whom. This information is central to evaluation of the adequacy and appropriateness of the document

b) Specifically consider sensitive populations, including children, people with diseases such as asthma or chronic obstructive pulmonary disease, pregnant females, the elderly, etc.

c) Perform some type of validation, which could range from a simple check to see that the relative ranking makes sense, to a quantitative assessment for those agents for which the ranking suggests action is warranted.

EPA is currently developing an indoor air toxics strategy to reduce risks from toxic air pollutants indoors, using non-regulatory, voluntary actions. The Science Advisory Board has supported an increased emphasis upon, and allocation of resources to address, the health importance of indoor toxics exposures and would offer our expertise and experience to assist with the formulation of the strategy through all stages of its development.

We look forward to a written response to the Committee's recommendations to make environmental technology performance measures more comprehensive and useful. Please contact us if we may be of further assistance.

Dr. William Glaze, Chair
EPA Science Advisory Board

Dr. Henry Anderson, Chair
Integrated Human Exposure Committee
EPA Science Advisory Board

Dr. Mark Utell, Chair
Environmental Health Committee
EPA Science Advisory Board

ENCLOSURE

JOINT EHC/IHEC REVIEW OF THE DRAFT DOCUMENT "RANKING AIR TOXICS INDOORS

REVISED

EXECUTIVE COMMITTEE REVIEW DRAFT

November 16, 2001

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DO NOT QUOTE OR CITE

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This advisory has been written as part of the activities of the Environmental Protection Agency (EPA) Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the EPA. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA nor of other agencies in the Executive Branch of the Federal Government. In addition, the mention of trade names or commercial products does not constitute a recommendation for use.

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ABSTRACT

TO BE SUPPLIED

U.S. Environmental Protection Agency
Science Advisory Board
Environmental Health Committee/Integrated Human Exposure Committee
Joint Meeting
July 19, 2001

CO-CHAIRS

Dr. Henry A. Anderson, Chief Medical Officer, Bureau of Environmental Health , Division of Public Health, State of Wisconsin Department of Health and Family Services, Madison, WI

Dr. Mark J. Utell, Professor of Medicine and Environmental Medicine, Pulmonary Unit,, University of Rochester Medical Center, Rochester, NY

SAB MEMBERS

Dr. Annette Guiseppi-Elie, Senior Consultant, Corporate Remediation Group, DuPont Spruance Plant, DuPont Engineering, Richmond, VA

Dr. Paul Foster, Program Director, Endocrine, Reproductive and Developmental Toxicology, Chemical Industry Institute of Toxicology, Research Triangle Park, NC

Dr. Michael Jayjock, Senior Research Fellow, Rohm and Haas Co., Spring House, PA

Dr. George Lambert, Associate Professor and Center Director, Center for Child and Reproductive Environmental Health, Environmental and Occupational Health Sciences Institute, UMDNJ, Piscataway, NJ

Dr. Grace LeMasters, Professor, Division of Epidemiology and Biostatistics, University of Cincinnati, Cincinnati, OH

Dr. Abby Li, Senior Neurotoxicologist, Regulatory & Toxicology Manager , Monsanto, Regulatory Division, St. Louis, MO

Dr. Ulrike Luderer, Assistant Professor, Department of Medicine, University of California at Irvine, CA

Dr. Randy Maddalena, Scientist, Lawrence Berkeley National Laboratory, Environmental Energy Technologies Division, Indoor Environment Department, Berkeley, CA

Dr. Barbara J. Petersen, President, Novigen Sciences, Inc., Washington, DC

Dr. Jed M. Waldman, Chief, Indoor Air Quality Section, California Department of Health Services, Berkeley, CA

Dr. Charles J. Weschler, Adjunct Professor , Department of Environmental and Community Medicine, UMDNJ, Piscataway, NJ

CONSULTANT

Dr. Stephen Brown, Risks of Radiation Chemical Compounds (R2C2), Oakland, CA

SCIENCE ADVISORY BOARD STAFF

Ms. Dorothy Clark, Management Assistant, 1200 Pennsylvania Avenue, NW, Washington, DC,

Mr. Samuel Rondberg, Designated Federal Officer, 1200 Pennsylvania Avenue, NW., Washington, DC

TABLE OF CONTENTS

1 EXECUTIVE SUMMARY

A Joint Committee, including Members and Consultants from the Environmental Health Committee and the Integrated Human Exposure Committee, met on July 19, 2001, to review a draft methodology for generating an order-of-magnitude, screening-level ranking of key indoor air toxics. The methodology was developed by EPA's Office of Radiation and Indoor Air (ORIA) as an outgrowth of the methodology used to select key pollutants for the National Air Toxics Program/Urban Air Toxics Strategy.

The Charge for the review , and the Joint Committee's findings, included the following issues:

a) Is the overall methodology suitable for the purposes of the ranking analysis (i.e., development of an "order-of-magnitude," screening-level ranking and selection of key air toxics indoors)?

In general, the Joint Committee finds that the methodology used in the Ranking document appears to be appropriate for the purpose of providing a preliminary "order-of- magnitude," screening-level ranking for selected indoor air toxics. Although it is recognized that indoor air may present a significant health risk, data are not available for a number of prevalent indoor air pollutants. As such, any method for ranking indoor air toxics will have significant limitations. The most serious problem seems to be omissions ~~in~~from the ranking of numerous toxicants of concern (e.g., "stealth" and criteria air pollutants listed below). These omissions are due to limitations in the available data used to complete the ranking, which are in turn due to limitations in the analytical methods, sampling approaches, and/or toxicological assessments. ~~Some effort should~~Efforts must be made ~~in examining~~to examine the biases caused by these limitations. The most important application of this tool may well be to define data gaps, so that better data can be generated in the most important areas. Furthermore, the ranking method can be improved by incorporating some indication of the likely ranges of exposures measured indoors.

The decision by EPA to use the current method will work, but only as a preliminary screening-level evaluation to provide the Agency with a relative ranking of selected chemical agents. Nevertheless, even ~~an~~a preliminary, uncertain and unstable ranking system will usually be preferable to no ranking system at all (random choice of pollutant for study) or a system that depends on the chemical-of-the-week syndrome or some other non-risk based set of criteria.

The report ~~needs to~~must define "air toxics" in the context of the ranking exercise and also explicitly explain why biologicals, radon and particulates are not included. Ideally, these important residential pollutants should be placed in the proper context (and most likely included in the ranking analysis). Also, the document should be revised to make it clear to the reader that lack of data or measurements for a given agent means only that data were not available or were not considered, not that the agent is considered to be of lesser (or greater) risk.

b) Are the criteria used to select the monitoring studies for the analysis appropriate? Are the studies chosen for the ranking analysis suitable, and are there other studies that you believe should be included in this analysis? Were the methods used to select and statistically analyze the data within the studies useful to the analysis?

The criteria listed in the draft document ~~seem to be~~are consistent with the objectives of the report. However, ~~they~~these criteria ~~need to~~must be much better defined.

Although the referenced studies span a large range of chemicals, they do not include most of the identified indoor chemicals of public health concern. A number of indoor pollutants that have been measured repeatedly and are known to be important are not included in this "Ranking." These include: Carbon monoxide, radon, asbestos, ~~PM2.5~~fine particulate matter, nitrogen oxides, ozone , and selected compounds associated with environmental tobacco smoke ~~(ETS)~~.

Additional explanation is ~~also~~ needed regarding the studies that were not selected and why. The report states that studies were not selected that included monitoring data that "contained specific chemical sources (e.g. smoking or specific products or materials)." The risk agents that were excluded should be clearly stated in the document along with the reason for exclusion. A limitation of the studies is that monitoring in several studies occurred during a very limited period, yet these values are used as lifetime daily exposure levels. Therefore, the mean value used for chronic exposure could be an overestimate or an underestimate depending on how representative the sampling period is of average yearly exposure for the chemical in question. This problem can only be corrected by obtaining better probabilistic based data that takes into account regional and seasonal differences.

c) Is the methodology for selection of the "risk-based concentrations" (RBC) (based on

that presented in the Technical Support Document for the National Air Toxics Program/Urban Air Toxics Strategy) useful in the context of this analysis?

The Joint Committee felt that the methodology for the selection of RBC was reasonable for purposes of a preliminary screening level ranking for selected toxics, but that the limitations of the methodology ~~could~~must be better explained. An appendix listing all the possible RBC for each chemical derived from each of the different data sources should be added, as well as a discussion of limitations in the toxicity studies on which the RBC were based.

d) How well have we described and addressed the adequacy, limitations, and uncertainties of the analysis, including:

1) Incomplete data on indoor concentrations and hazard/risk indices
2) Difficulties in determining the representativeness/accuracy of the “typical” levels indoors
3) The use of short-term monitoring data to represent chronic exposure periods
4) Issues related to the age of the data
5) Variations in the methods used by the various agencies to arrive at the health indices, which are the basis for the “risk-based concentrations?”

Limitations and uncertainties will be more or less important depending on the decisions that will be influenced by the results and the environment in which the decisions are made.

The results should only be used for a preliminary relative ranking, i.e., to identify the "top (those that potentially present the most substantial risks)" ranked or first tier chemicals versus ones ranked in the middle or lower tiers. Although an order of magnitude ranking will work, using the results as a surrogate for absolute risk is inappropriate because of the uncertainty in the database. To be explicit, the results should not be used for absolute ranking.

The Joint Committee also addressed some issues not specifically posed by the Charge, and made the following suggestions:

a) The document will be useful for initial screening, but it should be made clear as to what specific purposes for which it can be used, and by whom. This information is central to

evaluation of the adequacy of the document

b) In keeping with USEPA guidelines, this exercise should take into consideration sensitive populations, which include children, people with diseases such as asthma or chronic obstructive pulmonary disease, pregnant females, elderly etc. One Member noted, however, it was not clear how this goal could be accomplished without the application of considerably greater resources than had been devoted to this effort. This Member suggests that, given such resources, a feasible option might be to simply highlight those substances for which there are known highly susceptible groups not covered by the usual safety factors in the derivation of RBCs, or known higher exposures.

c) A "sensitivity analysis" to identify decisions and data gaps that have the greatest influence on the ranking ratios" would be useful.

d) The document should state clearly that lack of data for a given compound should not be taken to mean that the compound is of lesser or greater risk than compounds for which data were provided.

e) Before implementing any action the Agency should perform some measure of validation. This may range from a simple check to see that the relative ranking makes sense to a quantitative assessment for chemicals that the strategy would suggest action is warranted. Any quantitative evaluation should build on existing data and previous evaluations. It important to recognize and appropriately document that this ranking may be flawed because not all relevant chemicals could be included.

f) As the Agency is well aware, there are numerous studies that continue to develop data. It is not proposed that the Agency wait on these data to support the current strategy but that the strategy be subject to periodic (perhaps annual review) to take advantage of published data.

2 INTRODUCTION

2.1 Background

EPA is currently developing an indoor air toxics strategy to reduce risks from toxic air pollutants indoors, using non-regulatory, voluntary actions. To help focus their efforts on the most substantial risks, the Office of Radiation and Indoor Air (ORIA) has developed a draft methodology to generate an "order-of-magnitude" screening-level ranking and selection of key air toxics indoors. The ranking analysis used a methodology similar to that used to select key pollutants for the National Air Toxics Program/Urban Air Toxics Strategy, as presented in the Technical Support Document (TSD, 2000) for that program. The basis of the ranking is 10 monitoring studies chosen to represent typical concentrations of the pollutants found indoors. These data are combined with health-based indices (i.e., Risk-Based Concentrations, or RBCs, as defined in the TSD) to obtain ranking indices for both acute and chronic effects.

The ranking analysis will allow ORIA to identify those indoor pollutants that may present a greater risk indoors (based on the available data) , and then focus risk reduction efforts on the greatest opportunities for reducing risks through voluntary, non-regulatory risk management approaches.

2.2 Charge

a) Is the overall methodology suitable for the purposes of the ranking analysis (i.e., development of an "order-of-magnitude," screening-level ranking and selection of key air toxics indoors)?

b) Are the criteria used to select the monitoring studies for the analysis appropriate? Are the studies chosen for the ranking analysis suitable, and are there other studies that you believe should be included in this analysis? Were the methods used to select and statistically analyze the data within the studies useful to the analysis?

c) Is the methodology for selection of the "risk-based concentrations" (based on that presented in the Technical Support Document for the National Air Toxics

Program/Urban Air Toxics Strategy) useful in the context of this analysis?

d) How well have we described and addressed the adequacy, limitations, and uncertainties of the analysis, including:

1) Incomplete data on indoor concentrations and hazard/risk indices
2) Difficulties in determining the representativeness/accuracy of the "typical" levels indoors
3) The use of short-term monitoring data to represent chronic exposure periods
4) Issues related to the age of the data
5) Variations in the methods used by the various agencies to arrive at the health indices, which are the basis for the "risk-based concentrations?"

3 DETAILED RESPONSES

3.1 Suitability of the Overall Methodology for the Ranking Analysis

The first element of the Charge asked "Is the overall methodology suitable for the purposes of the ranking analysis (i.e., development of an "order-of-magnitude," screening-level ranking and selection of key air toxics indoors)?" The response to this issue is divided into two sections:

3.1.1. Is the methodology suitable for the purposes of a screening-level ranking?

The proposed approach could provide "order-of-magnitude" type rankings, and the Joint Committee agreed that the incorporation of both exposure and toxicity measures was appropriate. The Joint Committee notes that there are uses for a quick screening tool that utilize surrogates for exposure and associated risk. However, it must be clearly noted that such screening tools themselves do not assess exposure or risk. Therefore, the Members felt it is critical that the report clearly indicate the limited circumstances under which it is appropriate to apply the tool, as well as examples of when it would be inappropriate (as are discussed below). As a general comment, we might note that, as it is currently applied, the document's title is too general; a more accurate title to the report in its current form would be "Ranking Selected Indoor Organic and Metallic Air Toxics."

Moreover, the document should be clearer about how well an uncertain surrogate for risk performs in attempting to rank pollutants with respect to "real" risk. Presumably, an ideal ranking would rank highest those pollutants for which complete abatement would produce the greatest benefit in reduced cancer and non-cancer health effects in the U.S. population. No one really knows what these "real" risks are, so we use quotation marks and think of risk instead as what a state-of-the-art unbiased risk assessment would estimate. The quantitative nature (and its overall quality) of the ranking may then consequently degrade and become more qualitative in nature as the risk assessment is simplified by ignoring some of the parameters of risk. Such "lost" parameters would typically include the ~~(e.g., number of people exposed to each level of exposure)~~ and ~~using uncertain or non-representative information on the parameters preserved in the ranking (~~average or typical concentration levels~~; criteria for toxicity)~~. If the ranking index changes substantially from rank N to rank N+1 in comparison to the uncertainties in the data and the factors by which exposure differs from concentration, then those

uncertainties and simplifications will have relatively little impact on the ranking. Otherwise, the ranking may have very limited utility. Nevertheless, even ~~an~~a preliminary, uncertain and unstable ranking system will usually be preferable to no ranking system at all (possibly leading to a random choice of pollutant for study) or a system that depends on the chemical-of-the-week syndrome or some other non-risk based set of criteria.

The method makes no estimate of the potential population exposures (e.g. numbers of people) nor for the frequency or duration of exposure. Duration of exposure is potentially important. Some indications of the likely ranges of exposure in the population would make the ranking more useful – perhaps by including a measure of the range of body burdens in the ranking process.

EPA combined carcinogens and non-carcinogens together in the ranking of chemicals because of a stated need to set priorities for all of the compounds, regardless of the endpoint used. The Joint Committee recognizes this need, but recommended that it may still be useful to create and present a separate chronic Risk-Based Concentration (RBC) list for non-carcinogens and carcinogens. First, the risk assessment approaches are so different between carcinogens and non-carcinogens. Second, separating non-carcinogens from carcinogens will provide more focus for chemicals that have important non-carcinogenic effects that could be swamped out by combining carcinogens and non-carcinogens, even when using the 10^{-4} risk

Agents have been identified using 10 different studies that were chosen as having made measurements representative of "typical" concentrations of indoor pollutants. However, the analytical method chosen for a given study determines which subset of indoor pollutants is measured. For example, although all of the indoor environments sampled are expected to contain pesticides, only two studies actually measured indoor pesticides (EPA, 1990; Gordon, 1999). These studies were designed to sample, detect and quantify pesticides; the others were not. An analogous statement applies for polycyclic aromatic hydrocarbons (Sheldon 1992b) or metals (Clayton 1993). In other words, not all indoor pollutants are captured by these ten studies; only those that can be measured by the particular analytical procedures employed will be detected. Not only do different studies capture different pollutants, but even taken together these ten studies miss certain pollutants known to be present. For example, pyruvic acid is a human bioeffluent (208 mg/day/person; NRC, 1992) and will be present in any indoor environment that contains people. Yet none of these ten studies reported concentrations for

pyruvic acid; none of them were designed to sample and quantify this compound. Pyruvic acid is not expected to be a human health concern at typical indoor levels, but other undetected/unreported pollutants are less benign. Such pollutants include small, unsaturated aldehydes, certain highly oxidized compounds, thermally sensitive compounds, and short lived, highly reactive species that are not readily detected by analytical methods routinely applied to indoor air (Weschler and Shields, 1997a; Wolkoff *et al.*, 1997). Other examples of potential important toxicants include acrolein, methacrolein, butadiene, peroxyacetyl nitrate ~~(PAN)~~, brominated ethers, Criegee biradicals, the hydroxyl radical (Weschler and Shields, 1996; 1997b) and methyl peroxy radicals. **Given the above discussion, the document should be revised to make it clear to the reader that lack of data or measurements for a given agent means only that no data were available or were not considered, not that the agent is considered to be of lesser (or greater) risk.**

The Joint Committee recognized the limitations of the existing data and further noted that this exercise is really a ranking of those agents that have already been sampled and chemically analyzed. This implies that somehow these substances were already determined to have some level of concern in the indoor environment and that others are not of concern. In point of fact, other potentially important agents have not been determined because of difficulties in analytical methodology or because they were simply not (understandably) addressed by the available studies, which were done for purposes other than comparative rankings.

The reliability of this method is entirely dependent upon the reliability of the underlying data for both exposure and risk based concentrations (see below for further discussion of reliability of data sources). **Data were available that would permit estimation of a rank value for only 59 of more than 1000 potential indoor air pollutants**. In developing this method, the available studies were reviewed. Only a limited number of studies were of sufficient quality to use for this purpose (more than 50 studies were discarded). For some of the agents, there was inadequate indoor air monitoring (or the substance was detected less than 10% of the time). Much of the data are relatively old and may not be relevant to current indoor air pollutants. For example, the data on pesticide levels is more than 10 years, old and the EPA-approved uses for these chemicals have changed dramatically during that period. Many residential uses of those pesticides are no longer permitted, and, at the same time, new substances have been approved (It should also be noted, however, that many of these agents are very long-lived in the environment, and measurable levels may ~~will~~ persist in houses that have been treated

with them for years to decades after the last treatment (Delaplane and Lafage, 1990). Therefore, the data on these insecticides, although 10 years old, are not as irrelevant as they might first appear, although, ideally, one would like to know the persistence of each such agent. Other examples include chlorofluorocarbons, which are being phased out as a consequence of the Montreal Protocol, trichloroethylene, whose use has declined because of both health concerns and the Montreal Protocol.)

The sources of indoor air toxics (outdoor or indoor sources) drive consumer risk and exposure reduction response, but this model does not incorporate any measure of source-driven exposure. It may also be that the type of building (e.g., office, residence, school) is as important as other parameters and that the rankings would be more useful if the data were analyzed in terms of specific building types. From a purely biological standpoint, the human body does not artificially divide exposure between indoor and outdoor exposure, and it may be most appropriate to consider total potential exposure without distinction of the indoor/outdoor source. Some available data on personal exposures should be used to test the rankings, e.g. where there is additional information do we reach the same or different rankings?

3.1.2 Is the methodology as described suitable for the "selection of key air toxics indoors"?

The suitability of the method for assessing "air toxics" is dependent on the definition of "air toxics." The Joint Committee notes that many airborne substances (including biologicals, radon and particulates) found in the residential environment are excluded from the current ranking method. The report ~~needs to~~must define "air toxics" in the restricted context of this methodology, and also explain why biologicals, radon and particulates are not included. Ideally, these important residential pollutants should be placed in the proper context (and most likely included in the ranking analysis). It appears to the Joint Committee that the methodology would be equally applicable to all residential pollutants. Alternatively, the scope could be redefined to convey the more limited class of substances that are ~~to be~~ ranked. ~~As it is currently applied, the title is too general; a more accurate title to the report in its current form would be "Ranking Selected Indoor Organic and Metallic Air Toxics."~~

The overall methodology does not adequately account for the fact that the indoor concentrations of some "key" pollutants are marginally characterized. For example, most of the pesticide data are from just one study, conducted in two cities (EPA 1990). It addressed only a limited

subset of the housing stock, sampled between 1986 and 1988 before some of these pesticides were withdrawn from commerce. This one study yielded 6 of the top 16 compounds in Figure C7 (indoor mean/chronic case 1 Risk Based Concentration ~~(RBC)~~) and 6 of the top 14 compounds in Figure C13 (indoor-outdoor mean/chronic case 1 RBC).[1]

Although the referenced studies span a large range of chemicals, they do not include most of the identified indoor chemicals of concern. A number of indoor pollutants that have been measured repeatedly and are known to be important are not included in this "Ranking." These include: carbon monoxide, radon, asbestos, fine particulate matter~~PM2.5~~, nitrogen oxides, ozone , and selected compounds associated with environmental tobacco smoke ~~(ETS)~~. Although these substances may have been omitted from this ranking by design, the Joint Committee feels that it would be instructive to apply the ranking method to these "common" indoor air pollutants, if only to provide a set of benchmarks for understanding the rankings for the other substances.

The presentation of results in the report was admirably clear and straightforward. However, for chemicals where data are limited, it is recommended that, in the Figures (4.1, 4.2, and 4.3), an alternative symbol (other than the one for "Mean") be used when there is only one study. This is the case for metals (Clayton 1993), for pesticides (with the exception of chlorpyrifos and diazinon) (EPA 1990), and for polynucleated aromatic hydrocarbons~~PAHs~~: (Sheldon 1992).

The degree to which the data are nationally representative is critical. This issue includes geographical representativeness as well as for the target populations. Of particular concern to the Joint Committee is the need for unique rankings for exposures to children, since children have different activity patterns that need to be considered. There should be some consideration of those chemicals that may have a bigger exposure for children (e.g. substances preferentially found in carpets). (Further comments about special consideration of children's exposures are provided in section 3.5 of this report.)

The overall methodology for ranking the chemicals involved determining a risk based

[1]Only chlorpyrifos and diazinon are reported in Gordon 1999; all of the other pesticides come from EPA, 1990.

concentration for cancer and non-cancer endpoints. The risk based concentrations were obtained from recognized sources such as EPA IRIS (Integrated Risk Information System), EPA's Acute Exposure Guideline Levels ~~AEGL~~, the American Industrial Hygiene Association, etc. Although a flowchart that prioritized these sources was consistently applied for all the chemicals, the actual values selected came from variable sources with different levels of peer review and reliability, different approaches in selecting the most sensitive endpoint of concern and different application of uncertainty factors. The difference in reliability and consistency of risk management decisions within and across these different organizations can have an important impact on the relative ranking of chemicals. In addition, it is unclear the extent to which severity of effect is taken into account in deriving the risk based concentrations. The Joint Committee recognizes the difficulty of addressing these limitations, and, as stated above, advances it as an ideal. Nevertheless, an important step forward toward achieving this ideal is to make sure that this report provide the critical factors that inform how the risk based concentrations were derived. At a minimum, the Joint Committee recommends that for non-cancer endpoints, the report tabulate the critical endpoint, the type of study (e.g. dog chronic, rat teratology, human study), the Lowest Observed Adverse Effects Level (LOAEL) and No Observed Adverse effects level (NOAEL), and brief explanation of uncertainty factors that were applied (e.g. 10 intraspecies, 10 interspecies, 5 subchronic to chronic). For cancer endpoints, a brief description of the tumor type and study used, as well as the unit risk should be included.

In summary, the Joint Committee feels the method is suitable for initial screening-level ranking of selected toxic chemicals, but the participants are concerned about important omissions associated with the approach. The most serious problem seems to be omissions in the ranking of numerous toxicants of concern (e.g., "stealth" and criteria air pollutants listed above). These are due to limitations in the available data used to complete the ranking, which are in turn due to limitations in the analytical methods, sampling approaches, and/or toxicological assessments. The biases caused by these limitations ~~should~~must be addressed. The most important application of this tool may well be to define data gaps, so that better data can be generated in the most important areas. Furthermore, the ranking method ~~cant~~can be improved by incorporating some indication of the likely ranges of exposures measured indoors. To identify individual chemical data gaps it would be helpful to have a table that lists categories of information available for each of the ranked chemicals.

3.2 Use of Studies for the Ranking Analysis

The second Charge element asked "Are the criteria used to select the monitoring studies for the analysis appropriate? Are the studies chosen for the ranking analysis suitable, and are there other studies that you believe should be included in this analysis? Were the methods used to select and statistically analyze the data within the studies useful to the analysis?" These three inter-related questions are addressed separately below:

3.2.1 Are the criteria used to select the monitoring studies for the analysis appropriate?

The three criteria are listed on page 4 of the draft report:

a) Results presented were representative of typical concentrations in indoor non-industrial environments. Studies were not selected that contained monitoring data from buildings chosen because they had indoor air quality complaints, contained specific chemical sources (e.g., smoking or specific products or materials), were located near known outdoor sources (e.g., university laboratories or mining sites), etc.

b) Reasonably high confidence in validity of results, based on sample and analysis methods, and quality assurance procedures.

c) Data are of type and format suitable for inclusion in the risk ranking matrix.

These criteria are in line with the objective of the report. However, they need to be much better defined. In addition, the ORIA should discuss how the Building Assessment Survey and Evaluation (BASE) and School Intervention Studies (SIS) studies, which have not been published, meet the criteria established for the literature studies. By improving the discussion of the criteria used by the EPA to select studies, the Agency can be much more specific about what they want to rank and, more important, what they think they can (or cannot) rank.

The first criterion really defines the breadth of the approach. Although the report identifies "typical concentrations in indoor non-industrial environments" as the focus of the ranking, several other things should be included when using "representative" as a selection criterion. At a minimum, the first criterion should specify *where* (urban regions, agricultural regions, the contiguous U.S., …); *who*

(adults, children, male, female, a probability based sample of the non-institutionalized U.S. population, …); *when* (retrospective analysis, prospective analysis, long-term average, short-term average, …); and for *what* chemical(s) (all chemicals, measurable chemicals, volatile organic compounds~~VOCs~~, metals, pesticides, …) and media (indoor/outdoor air, personal air, house dust, surfaces, foods, …). This is also the place to identify the exposure pathways that are included in the ranking process (inhalation of indoor air) and which are excluded (dietary and non-dietary ingestion, dermal, all outdoor pathways and indoor pollutants of outdoor origin).

Additional explanation is also needed regarding the studies that were not selected. The report states that studies were not selected that included monitoring data that "contained specific chemical sources (e.g., smoking or specific products or materials)." The risk agents that were excluded should be clearly stated in the document along with the reason for exclusion. In some cases, the chemicals may have been excluded because a separate effort was made to specifically address these chemicals (e.g.. radon). If so, this should be clearly stated and referenced. In other cases, a few sentences are needed to clarify some apparent discrepancies in selection of literature studies. For example, the report states that monitoring data that contained specific chemical sources such as smoking were omitted, yet several of the literature studies that were included clearly measured chemical exposure in households which had smokers. In addition, the BASE study evaluated data from 100 randomly selected office buildings which did not strictly follow the described selection process for literature studies.

In defining the second criterion of what contributes to a "reasonably high confidence in validity of results," the Agency should include the level of peer review for the study/data. This recommendation is in addition to the adequacy of the sample and analysis method and quality assessment/quality control~~QA/QC~~ procedures that are already specified as important. The Joint Committee did not examine the BASE and SIS studies, but the revised ranking methodology document should include a discussion noting the type of peer review to which these studies were subjected. ~~Since the data are not published~~Even though both of these studies were published as EPA reports, it is imperative that the full data set be made available so they can be independently checked.

For the third criterion, it ~~might~~would be helpful to state exactly what format is needed and what types of data transformations might be acceptable. For example, the arithmetic mean is identified in the report as the most desirable measure of central tendency. However, a number of studies only report

the geometric mean ~~(GM)~~ and geometric standard deviation~~(GSD)~~. This criterion might specify that for these cases, the EPA will assume that the data are lognormally distributed and use the reported geometric mean~~GM~~ and geometric standard deviation~~GSD~~ to estimate the arithmetic mean. EPA indicated in the presentation at the public meeting that they conducted a comprehensive literature search first and then narrowed down the number of studies from 65 to 10. EPA should explain this process in the report and list the studies that were considered and failed to meet the selection criteria in an appendix or at least report the years that were searched. Sufficient details about how and when the search was performed should be provided so that when/if the study is updated then the search effort won't need to be duplicated.

3.2.2 Are the studies chosen for the ranking analysis suitable, and are there other studies that you believe should be included in this analysis?

From the exposure standpoint, the suitability of the studies depends on the overall purpose of the analysis, which should be spelled out in the study selection criteria as discussed above. If the question is whether the studies provide an informative case for demonstrating the ranking methodology with a limited set of chemicals, then the selected studies are adequate. However, if the goal is to provide a ranking across the universe of chemicals in the indoor environment then the selected studies clearly fall short of the mark and the results are inappropriate. Although it ultimately depends on how "representative" is defined in the study selection criteria, a set of studies that represent a probability-based sampling of all indoor non-industrial environments in the U.S. during the past, present or future does not exist and will almost certainly not exist any time soon. Given the severe limitations of direct monitoring data, it might be advisable to consider supplementing the approach with a "screening level" indoor fate and exposure model to draw upon other sources of information (i.e., emissions data, chemical use data, activity data, …).

Care should be taken to insure that the "compound" identified in the monitoring studies matches the "compound" addressed in the ranking analysis studies. This statement applies to the metals, not the airborne organic compounds. In the case of the metals, the speciation is very important --- oxidation state and associated ligands (e.g. in the case of transition metal complexes, the organic compounds coordinated to the metal center). For example, manganese (Mn) has been identified in the appropriate monitoring study (Clayton 1993) by x-ray fluorescence. This analytical method provides no information

on the actual chemical(s) that contain Mn. Mn has significantly different bioavailability in its different chemical forms. Without knowing Mn's speciation in indoor air, it is not possible to properly match its airborne concentration to a risk.

3.2.3 Were the methods used to select and statistically analyze the data within the studies useful to the analysis?

A limitation of the studies is that monitoring in several studies occurred during a very limited period, yet these values are used as lifetime daily exposure levels. Therefore, the mean value used for chronic exposure could be an overestimate or an underestimate depending on how representative the sampling period is of average yearly exposure for the chemical in question. This problem can only be corrected by obtaining better probabilistic based data that takes into account regional and seasonal differences. These limitations aside, the mean is a more stable estimate than the 95th upper limit for purposes of determining relative rank because the mean reflects the central tendency and is less influenced by range of values in the data set.

The treatment of uncertainty in the report is somewhat inconsistent. Although the ranking ratios are calculated and plotted for each data source providing a range of values, information about the variance associated with these measurements for each building/study is lacking. In addition to variability across similar building types, the sources, distribution processes and removal mechanisms for indoor pollutants will vary between residences, office buildings and schools (this was noted in Section 6.1 of the report). However, this variability/uncertainty is not captured in the ranking ratio. Even if the EPA assumes that there is no uncertainty in risk-based concentration (RBC) for policy reasons, uncertainty reported for the measured concentrations can and should be propagated through the calculations to provide estimated confidence intervals for the ranking ratio. (See section 3.4 of this report for a full discussion of uncertainty issues.)

EPA used different values for means, undetected samples, and upper limit primarily because the different studies reported data differently. If the primary goal is to determine relative ranking of chemicals, then it would seem that consistency of values used would be desirable. There were different opinions among SAB members as to the relative contribution of this difference to the ranking in light of other uncertainties. As a specific example, one-eighth of the limit of ~~quantization~~quantification ~~(LOQ)~~

was assigned to undetected samples in some cases and one-half of the limit of ~~quantization~~quantification ~~LOQ~~ in others. The rationale was to use values that were internally consistent with each of the studies. It is possible that the value used for non-detects could make a significant difference to calculation of exposure and hence to the risk-based ratio especially for those chemicals with large numbers of non-detects. How much of a difference this makes depends on the risk based concentration for each chemical. In other words, the contribution of the variability resulting from difference in assignment of values for non-detects is not simply 4-fold. Until a sensitivity analysis is conducted, it is difficult to determine how significant these differences would be to the ranking analysis. Given that there were only 10 literature studies that required follow up, it would have been possible for EPA to obtain raw values in order to conduct a uniform analysis. Since EPA will be using these studies as basis for recommending action, it may be prudent to have the data supporting these literature studies in hand and undertake the above sensitivity analyses.

The difference between indoor and outdoor concentrations is commonly used as a surrogate for identifying indoor sources. Joint Committee Members expressed concerns about using this simplistic model which, as indicated in the report, can overestimate the influence of outdoor sources resulting in a lower ranking for a given indoor pollutant. For the chemicals included in this ranking, using the indoor/outdoor difference did not seem to significantly alter the ranking for the chemicals in the upper 20%. Therefore, to reduce the chance of removing a potentially important chemical from the list, we recommend that all of the chemicals measured in the indoor air be included in the ranking process but those suspected of being predominantly of outdoor origin should be flagged or identified in the text. Characterizing the source of the pollutant is important, but it is too complicated and poorly understood to include in the "order-of magnitude" screening method presented here. Removing the indoor/outdoor results would also have the benefit of reducing the number of outcomes to three (Chronic/Cancer; Chronic/Non-Cancer; and Acute/Combined) rather than six.

One of the key strengths of this report is that it highlights the limitations of existing monitoring data. To take full advantage of this strength, the chemicals that were considered but removed from the ranking process should be documented in a separate table or an appendix. If a chemical was removed from the ranking because of inadequate monitoring data or lacking toxicity data then that is very useful information, and it should be noted. Detection of a chemical less than 10% of the time may be an indication that exposure to that chemical is episodic, but real, so completely removing these chemicals

may be misleading both to the decision maker and the public, particularly when these are low frequency, high concentration events and if the outcome of concern is acute.

There seems to be an implicit emphasis on volatile organic compounds ~~(VOC)~~ and adults in that only indoor air concentrations are considered. Expanding the ranking approach to include surrogate data for other exposure pathways (i.e., house dust and surface wipes related to non-dietary ingestion and dermal contact by children) would improve the way semi-volatile chemicals and metals are considered. However, including semi-volatile organic compounds ~~(SOC)~~ and metals correctly would significantly increase the complexity of the ranking procedure (semi-volatile organics~~SOCs~~ are present in the gas phase as well as in the condensed phase (on the surface of particles, carpets etc.); they are partitioned between these two phases). If this is beyond the scope of the report, then it should be noted that a number of exposure media and exposure pathways were excluded from the analysis (see discussion of study selection criteria).

As previously noted, it would be helpful to include a sensitivity analysis to identify the decisions and data gaps that have the greatest influence on the ranking ratios. A range of sensitivity analysis methods are available (Saltelli and Chan, 2000), and many of them can be used without a significant investment of time and resources.

3.3 Methodology for Selection of the "Risk-based" Concentrations

The Joint Committee was generally satisfied that the methodology is reasonable for the purposes of ranking. The use of a level of cancer risk equivalent to exposure at the reference dose~~RfD~~ is a rational way of making cancer and non-cancer risk analyses comparable. The use of two risk levels (10^{-6} and 10^{-4}) is a reasonable way of showing the sensitivity of the analysis to risk management preferences. EPA rarely uses risk levels outside that range as criteria for the acceptability of exposure. The use of a hierarchical scheme of data preference is commonplace for ranking systems. There were a few concerns and several suggestions provided by the Committee.

Figures 4.1 through 4.3 in the draft report were very helpful in reducing complicated procedures to a straightforward format. Further details explaining the methodology presented in these figures for generating RBC and operational definitions for key terms such as RBC are needed. It is

unwieldy to use reference documents to understand these essential terms.

Overall, the RBC seem appropriately conservative given that the purpose of this process is to provide a screening level ranking of indoor air toxics. Preference was given to more protective risk estimates rather than less protective exposure limits like occupational exposure limits, which are not designed with the most sensitive individual or with the potential for lifetime exposure in mind. On the other hand, many of the sources on which the RBC were based are likely to have used toxicology studies on adult animals. If developmental toxicity studies were included, however, they are apparently traditional developmental toxicology studies in which embryos are examined towards the end of gestation. These studies do not evaluate more subtle developmental toxicity such as effects on the reproductive, immune, and nervous system that are manifested later in life. Thus, it could not be readily determined if the RBC was based on data or risk management decisions that took into consideration potential differences in susceptibility between children and adults. The report should include a table that lists the critical endpoint, study type and species, and brief description of uncertainty factors or unit risk used to derive the RBC. EPA should also address how the RBC, and ultimately the rank order, is or is not relevant to children Given that children and pregnant adults may be the most susceptible populations in the indoor environment, additional consideration should be given as to the impact of these rankings on these two groups. Almost all the Members of the Joint Committee find merit with this concept, i.e., providing a dual ranking priority system (one designed for susceptible populations and another for less susceptible groups). ~~One Member disagrees~~Two Members disagreed, however, noting that the derivation of the RBC takes into account sensitive sub-populations and is sufficiently conservative for this order-of-magnitude ranking scheme, and that further analyses of specific chemicals should evaluate effects on sensitive populations.

A quality control check was performed on four chemicals. Two were straightforward, because RBC from the Integrated Risk Information System (IRIS) were used. When RBC were gathered from other databases the process was not easily reproduced. One possible explanation for this lack of replication may be related to the frequent updates of the California EPA (CalEPA) database. Thus, if the date on which the RBCs are abstracted from the databases are provided as footnotes in Table B3, this confusion will be avoided. One or two examples outlining generation of the ranking ratios from beginning to end ~~will facilitate~~is needed to assure better understanding.

One issue that was raised concerned the dated information on IRIS. If California Environmental Protection Agency (CalEPA) databases are a more current data source, then perhaps the order of preference should be altered. However, the inherent policy decisions in both databases should be evaluated before making such a decision. Information as to the quality control checks already completed by the EPA on the entire methodology should be provided.

Concern was expressed that use of a purely hierarchical selection process when there are several available RBCs seems to waste information. Why not compare the different available RBCs and make an assessment as to the weight of the evidence? Criteria could include how up-to-date the studies are that were used to determine the RBCs, what assumptions were made in converting animal data to human data, etc. The discussion of limitations on page 19 addresses this somewhat in that it explains that for most compounds there was only one available RBC. However, the example of benzene (for which there were several RBCs) indicates a three-order of magnitude difference in RBC from among four sources. The Joint Committee recommends that ORIA include an appendix showing the different possible RBCs for those compounds for which there were multiple options, as was done in the California Office of Environmental Health Hazard Assessment (OEHHA) Air Toxics Risk Assessment Guidelines for cancer unit risk values. In this regard, the participants also recommend that the endpoint on which the RBC is based be included in the tables.

Another issue identified concerned the question of why the ranking of sources for chronic and acute RBCs changed compared to the Technical Support Document ~~(TSD)~~. The Joint Committee noted the following changes:

a) For the acute RBC, Cal OEHHA Reference Exposure Levels have been moved down to fourth from second and American Industrial Hygiene Association Emergency Response Planning Guidelines moving from third to second.

b) For the chronic RBCs the Cal OEHHA Reference Exposure Levels have been moved up and the EPA Health Effects Assessment Summary Table (HEAST) moved down in ranking. Which of these, if any, were derived with the general population, including more sensitive individuals, in mind? Those factors would be the most appropriate to use for the current purpose.

c) National Institute of Occupational Safety and Health (NIOSH) Immediately Dangerous To Life and Health (IDLH) moved from fourth to third. For the NIOSH IDLH, has the value derived from dividing by 10 been compared to the acute one-hour mild values for compounds for which there are IDLHs, ERPGs, and Reference Exposure Levels available, to determine whether they are comparable?

For carcinogens, the risk estimates that were given priority were derived using linear multistage modeling, which assumes no threshold effects, and thus predicts higher unit risks than other models. For extrapolation from humans to animals, doses were converted based on surface area (0.67 power of body mass), rather than body mass. The former is the more protective approach. Finally, for cancer, the more protective 95% upper confidence limits rather than means were used. For non-carcinogens, preference was again appropriately given to the more conservative risk estimates. The EPA Reference Concentrations (RfC), Agency for Toxic Substances and Disease Registry Minimum Response Level (ATSDR MRLs), and Cal OEHHA Reference Exposure Levels ~~RELs~~ were used for determination of chronic non-cancer RBC. Most of these are derived by applying a standard uncertainty factor of 10 for interspecies extrapolation and another factor of 10 for inter-individual extrapolation to the No Observed Adverse Effects Level (NOAEL) for a chemical, resulting in a protective limit. Combining the cancer risk estimates and the non-cancer based risk estimates is a good approach for a screening level process and the use of two cancer risk levels permits the capturing of non-cancer chronic health effects that would have been "swamped out" by using only the 10^{-6} risk levels.

Ranking is not sensitive to a consistent bias in health-based concentration criteria. That is, if all EPA unit risk factors are overstated by the same factor, then the pollutants will not be mis-ranked . However, if health indices are inconsistently conservative (either within the EPA, IRIS system, or across agencies), the potential for mis-ranking arises. This deficiency of using criteria with conservative, but inconsistent, biases is well known to be a problem for ranking systems, but probably cannot be avoided in the absence of a data set based on central or "best" estimates of toxicity criteria. Furthermore, the rankings cannot be interpreted to say anything about absolute risk. These issues ~~might~~should be discussed in the document.

A voluminous amount of information was well summarized in Tables B1 – B9. These tables

were presented in a straightforward and easily interpretable manner. Footnoting of the tables is needed, however. What appeared to be possible inconsistencies in the tables were not explained. For example, Table B1 lists four studies for styrene, with four having indoor building data. One of the studies indicated (in Table B1 of Daisey's 1994 article) that 12 buildings were studied. The frequency of detection is indicated as 88%, but no number of indoor observations is listed. These data appear inconsistent and confusing and can be easily explained with a footnote. Also, another table might be added to summarize each chemical, organized by the ranking ratio it achieved via each methodology. This new table (B10) will assist the reader in assimilating the important information from tables B4 through B9 without having to flip back and forth.

Each ranking ratio methodology produced a different set of ranking ratios for the majority of the chemicals. The top ranked chemical, formaldehyde, was the exception, generating a rank of 1 on each table. The rankings for certain specific air toxics were surprising to some Members, particularly for the acute ranking. For example, ethanol and acetone ranked 12 and 13 in Table B5, whereas acute toxicity from these substances in indoor air seemed unlikely to these Members. The explanation probably lies in the linearity implicit to the ranking, as it does not deal with thresholds of toxicity. Thus, the high ranking of ethanol and acetone is being driven by airborne concentrations, Some comment on this limitation of the rankings is desirable, as there was concern about the ultimate interpretation of the process and the results by both scientists and consumers.

In conclusion, the Joint Committee felt that the methodology for the selection of RBC was reasonable for purposes of a preliminary screening level ranking for selected chemicals, but that the limitations of the methodology could be better explained. First, an appendix listing all the possible RBC for each chemical derived from each of the different data sources should be added, allowing some of the information lost by using a strictly hierarchical approach to selection of the RBC to be retained. Second, a discussion of limitations in the toxicity studies on which the RBC were based should include some indication that studies evaluating effects on sensitive subpopulations such as children and pregnant women were probably lacking for most chemicals. Third, the endpoint on which each RBC was based should be included in Table B3. ~~Finally, the data from which the RBC were abstracted should be included in the table so readers know what version of the value was used.~~Finally, the table should be modified so that readers can determine what version of a given data set was used to generate a specific RBC.

3.4 Adequacy, Limitations, and Uncertainties of the Analysis

The Joint Committee first provides an answer to the general question of Charge 4 and then addresses each of the more specific sub-questions posed by the Charge

Clearly, the adequacy of the analysis depends on how well it can serve its purpose. Limitations and uncertainties will be more or less important depending on the decisions that will be influenced by the results and the environment in which the decisions are made. It does not make sense to devote too much effort to improve the ranking system if that would significantly decrease the Office of Radiation and Indoor Air's (ORIA) resources for actually dealing with indoor air toxics. On the other hand, if ORIA's decisions will greatly impact those responsible for indoor air quality in residences, schools, and office buildings, then a flawed ranking can lead to serious mis-allocation of public resources.

According to the request for review provided to the SAB, the draft document was developed to help focus ORIA's efforts on "the most substantial risks" as EPA develops its indoor air strategy. The document attempts to present an "order-of-magnitude", screening-level ranking using similar methodology to that used to select key pollutants for the National Air Toxics Program/Urban Air Toxics Strategy. EPA's indoor air strategy will likely use non-regulatory, voluntary incentives to reduce risks from indoor pollutants. The document itself states that its purpose is to "provide a screening-level prioritization scheme for air toxics indoors [to identify] those pollutants that may present a greater risk indoors . . ."

However, exactly what options will be prioritized remains unclear. Can ORIA develop a control strategy for any indoor pollutant, or only those with more complete data sets? Is population risk (in the sense of the annual incidence of debilitating health effects) the principal concern? How important are pollutants that might not affect a large population, but would place disproportionately high risks on a smaller population, such as the most highly exposed group or some vulnerable or valued group such as children? To what extent can ORIA gather more information to improve the ranking, or must it rely on existing data? A ranking of research priorities would be different than a ranking of action priorities based on current information.

ORIA should be sure that the quality of the ranking system matches the needs of the uses to

which it will be put. As it stands, the system only addresses that part of the universe of indoor air toxics that are "under the lamppost" in the sense of having sufficient data available for ranking with the current algorithm. The Joint Committee noted that use of default values or model results for missing data could expand the universe to be ranked, but of course with correspondingly uncertain results. Such a strategy could at least help identify those pollutants that *could* be important, and suggest where research might have the greatest payoff. As it stands, the system is more useful as a screening exercise to identify those pollutants that are not likely to be high in risk relative to the highest ranking of the qualifying pollutants. It may not be adequate to identify a few indoor air toxics that deserve significant resources for development of a control strategy.

With a few exceptions, the document adequately describes and discusses the major uncertainties of the analysis in qualitative terms. Improvements in the treatment that might enhance the utility of the document and its transparency to readers include:

a) A better statement about what constitutes adequacy, limitations, and uncertainties for a ranking system. In the opinion of the Joint Committee, the key question is how often might the Agency focus on an indoor air pollutant that poses relatively low "real" risk at the expense of deferring attention to an indoor air pollutant with relatively high "real" risk. (See our comments about risk-based ranking ~~earlier~~ in section 3.1.1 of this report to understand why the word "real" is in quotation marks.) Only limitations and uncertainties that lead to substantial mis-ranking are important in judging the adequacy of the ranking method and data.

b) Some discussion of quantitative measures of uncertainty is needed. Although the Joint Committee recognizes that the available data are not extensive and prevent easy quantitative characterization of uncertainty, the document could at least compare the typical uncertainty in average concentrations (as represented by the standard deviation on the mean concentration) with the range of ranking indices. For example, Figures C-7 to C-9 suggest that the ranking index varies from about $3x10^{+2}$ to $1x10^{-4}$ for the chronic Case 1 analysis, a range of over six orders of magnitude. If the uncertainties in the concentration data are indeed "order of magnitude" in the sense of being within a factor of 10 of the true population- and time-weighted average concentration, then that

uncertainty would only change rankings by perhaps 10 places, and rarely would a pollutant ranked in the bottom third of the list actually deserve ranking in the top third. Uncertainties of a factor of 10 in the RBC will have essentially the same impact on the quality of the ranking. Of course, if ORIA can only address one or two of the indoor air pollutants at a time, the influence of uncertainty will be greater than if it can address 20% of the list at a time.

c) The Joint Committee is not entirely comfortable with the document's explanation of the superiority of monitoring data to model results. Models, if properly calibrated and validated, can sometimes compensate for deficiencies in monitoring data caused by changes in exposure (e.g., the cancellation of pesticide registrations mentioned), short-term vs. long-term monitoring, etc.

d) The uncertainty section does not mention children or other subpopulations. It is important to describe how they are or are not included in the analysis. The report does not provide sufficient information to determine if the rank order is relevant for children. At a minimum, the report should address this or consider it a limitation of the analysis.

e) The treatment of uncertainty in the report is somewhat inconsistent. Although the ranking ratios are calculated and plotted for each data source, thereby providing a range of values, information about the variance associated with these measurements for each building/study is lacking. In addition to variability across similar building types, the sources, distribution processes and removal mechanisms for indoor pollutants will vary between residences, office buildings and schools (this was noted in Section 6.1 of the report). However, this variability/uncertainty is not captured in the ranking ratio. Even if the EPA assumes that there is no uncertainty in RBCs for policy reasons, uncertainty reported for the measured concentrations can and ideally should be propagated through the calculations to provide estimated confidence intervals for the ranking ratio.

f) Until a sensitivity analysis is conducted, it will remain difficult to determine how significant differences in the treatment of non-detects, the measure of central tendency, and other study design choices are to the ranking analysis. As noted earlier in this

report, a range of sensitivity analysis methods is available, and many of them can be used without a significant investment of time and resources.

3.4.1 Incomplete Data on Indoor Concentration and Hazard/Risk Indices.

The consensus of the Joint Committee is that the analytical methodology is appropriate but the available data are definitely lacking relative to providing a screening level analysis for indoor air toxics. It is clear that all or perhaps even most chemical species salient to human health risk are not included in the current database. This limitation is born of the paucity of exposure and health effects data. Thus the analysis is useful for a well-defined universe of specifically identified agents but can not claim to screen existing risk from indoor air pollutants in general. It is therefore important to recognize and document more fully the fact that this ranking ~~may be~~is flawed because not all relevant chemicals could be included. The document points to the lack of data for "thousands of chemicals," but perhaps this could be placed in better context for what it means for the use of the results by this ranking method. Similarly, there should be a clearer explanation of why agents like radon and biologicals are not addressed.

One approach to including more relevant air toxics into the analysis is to consult with those within the EPA working on Design for the Environment ~~(DfE)~~ projects. This group has studied important indoor air sources and has facilitated the development of the Wall Paint Exposure Model ~~(WPEM)~~ as a state-of-the-science modeling tool that predicts the long-term time course of indoor air concentration from paint concentration. **(EPA, 19XX)**

The most challenging part of doing a more comprehensive analysis of indoor air toxicants will be in the identification and characterization of the most important species. General air monitoring in a screening analysis for hundreds of volatile, semi-volatile and oxygenated species would be very useful. Several organizations have pioneered a number of techniques relevant to this area that may be of value to the Agency.

On the hazard/risk indices, a discussion of the specific methods used in developing hazard/risk indices from the various sources and their inherent limitations and/or biases would be appropriate. The use of a hierarchy is acceptable, once it can be shown that there is not systematic bias or that those

biases are addressed.

3.4.2 Difficulties in Determining the Representativeness/Accuracy of the "Typical" Levels Indoors

Representativeness and accuracy of the "typical" indoor levels are very important in identifying those indoor pollutants that present substantial risks indoors. As noted earlier, this begs for a definition of "typical" and “representativeness,” because it is accepted that these measurements are not accurate. It would appear that as many varied settings were used as available, e.g., residences, offices and schools. Combining these different data would produce a larger database and improve statistical power, but it would make even more difficult drawing a conclusion about “typical and representative” because the environments are so different. Some evaluation of specific indoor settings would be better to draw conclusions about representativeness for a given setting (homes only, schools only, etc). Other than this, it should be made clear that these are simply attempts to rank indoor air concentrations and make no claims about representativeness.

Useful estimates of "typical" levels are possible, given a sufficiently large database of representative subjects. This is essentially a statistical question; however, it is fairly obvious that the limited data available in this work are not large enough to assure a high level of confidence in these estimates, and perhaps confidence limits around the estimates will help.

3.4.3 The Use of Short-term Monitoring Data to Represent Chronic Exposure Periods

Although the Joint Committee is satisfied that short-term measurements are reasonable to use to represent long-term averages for the purposes of ranking, additional discussion of the possibility of bias in the draft document, as well as suggestions for dealing with bias when it is identified, would be welcome. For example, if all the studies for a particular pollutant were conducted in summer when ventilation rates might be higher and indoor concentrations from indoor sources lower, then their rankings would be biased low in comparison to a pollutant with more representative year-round measurements. A similar problem might exist if different LOQ strategies were employed for different pollutants.

Another concern is that some toxins could have more significant effects depending on when (in the life cycle of the exposed human) exposures take place, e.g., causing birth defects in the fetus or neuro-developmental changes in infants. In this context, short-term measurements may not relate accurately to significant exposures, unless the studies were looking specifically at sensitive populations (see also the discussion of sensitive populations in section 3.5 of this report).

Any attempt to propose action would require a more detailed evaluation of the relevance of the timing of health effects based on exposure.

3.4.4 Issues Related to the Age of the Data

EPA acknowledges that the pollutant concentration data on which the ranking is based are dated. This problem is inherent in any ranking situation in which the conditions of exposure are changing with time. Therefore, the conclusions can stand, if used to define relative ranking, but in this instance more than any other, validation is required to ensure that unwarranted action is not being proposed.

The results should only be used for relative ranking, i.e., to identify the "top (those that potentially present the most substantial risks)" ranked or first tier chemicals versus ones ranked in the middle or lower tiers.

Although an order of magnitude ranking will work, using the results as a surrogate for absolute risk is inappropriate because of the uncertainty in the database. ~~To be explicit, the results should not be used for absolute ranking.~~

The results should not be used for absolute ranking. Before implementing any action, EPA should perform some measure of validation. This may range from a simple check to see that the relative ranking makes sense to a quantitative assessment for chemicals proposed for control strategies. Any quantitative evaluation should build on existing data and previous evaluations.

Finally, as the Agency is well aware, there are numerous studies under way that will develop relevant data. Examples include toxicity testing data being generated under the high production volume

(HPV) program and exposure data being generated by the National Urban Air Toxics Research Center (NUTRC) on apportionment between indoor, outdoor and personal exposures. It is not proposed that the Agency wait on these data to support the current strategy but that the strategy be subject to periodic (perhaps annual) review to take advantage of published data.

3.4.5 Variations in the Methods Used by the Various Agencies to Arrive at the Health Indices

The discussion of the influence of different approaches to health indices among the agencies could be improved by noting whether there are consistent differences (e.g., are the ATSDR MRLs consistently higher than EPA Reference Concentration when both agencies have published results for the same pollutant?). If that were true, then a pollutant ranked with an ATSDR MRL might fall lower on the list than a similarly risky pollutant ranked with an EPA Reference Concentration.

The Joint Committee suggests that the hierarchy of RBC methods be "calibrated" by comparing a number of materials that have RBC in all or most of the available methods. These RBCs could then be compared to each other to determine any level and type of systematic differences between them. For example, one could describe a distribution of ratios of estimates from one to another and the parameters of the distribution might be useful in determining adjusting factors that would "even out" the estimates from each in a less biased ranking scheme.

An important limitation of the toxicity component of the ranking is that the severity of effect, or level of concern, is not considered in this screening level ranking. Taking severity into account is not an easy task because it requires subjective assessment. However, at a very basic level, additional columns or a new table should be added that identifies the critical effects that are the basis for the risk based concentrations, the uncertainty factors applied, and the unit risk for carcinogens. It should also be noted that the underlying assumption of life-time chronic exposure may not be appropriate for all chemicals evaluated for chronic toxicity. A consideration of actual duration and level of exposure can make an important difference to the toxicological outcome and hence to whether the risk-based concentration used is relevant.

The differences among the sources for the RBCs need to be more clearly stated rather than

referring to the Technical Support Document for Hazardous Air Pollutants (outdoors). It is important to recognize the inherent policy positions that are taken in each method and ensure that these are explicitly noted. An evaluation to show the level and direction of "bias" (i.e., does one database consistently provide higher or lower values) would provide an additional basis for determining whether overall the hazard/risk indices are consistent and provide meaningful results. The question to be addressed is: are the different indices supportive of each other or divergent and if the latter is there a plausible, defensible reason.

3.5 Additional Issues

The Joint Committee identified several issues and concerns not specifically addressed in the Charge:

a) 2,3,7,8-tetrachlorodibenzo p-dioxin was not on the tables but is referred to in text.

b) EPA recently developed the National Air Toxics Assessment (NATA) and subjected it to SAB review. It is a first cut at a risk assessment of air toxics from outdoor sources. Interestingly, neither the NATA nor this proposed methodology document cite one another. One of the criticisms of NATA is that it does not address total exposure because it does not deal with indoor sources and one of the criticisms of this indoor report is that it does not address total exposure, eliminating consideration of outdoor sources. Some of the methodology is different across the two documents. It is not possible to redo each of these documents with consistency, but each should acknowledge the other and discuss the issue of air toxics risk from the viewpoint of the total exposure of the person.

c) The authors of the report are not listed and there is no indication of other peer review. Traditionally, names of authors and reviewers are provided to give credit to the hard work involved, but also to let other reviewers understand the likely technical attention paid to elements beyond the scope of the SAB review. For example, were any authors/reviewers expert in toxicology, exposure and environmental air monitoring to enable judgments on the quality of the data used from unpublished studies and different

agency risk based concentrations?

d) The document will be used for screening, but it is not clear for what additional future purposes and by what entities. This information is central to evaluation of the adequacy of the document.

e) As noted above, children's specific health issues were not considered , nor were issues pertaining to any group of humans that may have heightened sensitivity to these chemicals. This is probably due to a lack of data on these chemicals and their relative effects on the developing animal or the developing human.

In consideration of indoor air pollutants, child specific factors have to be taken into consideration if the prioritization is to have its greatest reliability and acceptance.

1) Children may have higher risks from a given exposure than do adults, due to their neuro developmental status or smaller size. The child may be exposed to chemicals that are found at higher concentration at infant/child height than at adult heights. The higher concentration of these chemicals at the lower heights in rooms may be due to the air pollutants being emitted from materials that are found at lower heights such as floor coverings (rugs, varnish, etc), or chemicals that are sprayed on the floor (pesticides), or pollutants that are heavier than air and are found at higher concentration at lower levels. However, such exposure assessments are complex, since convective mixing in most indoor settings may be more than sufficient to prevent this type of stratification for contaminants present at ppb levels. Furthermore, the different exposure routes for children, such as dermal and via ingestion, need to be considered.

The child also has a higher exposure from a physiological and pharmacokinetic basis. The child has a higher tidal volume and relative higher respiratory surface area per kilogram as compared to the adult or the elderly. This results in the child breathing in more air pollutants and absorbing more chemicals from the air than the adult breathing the same air pollutants. Once they are absorbed, the

child may clear the chemicals at a slower rate than the adult (although it should be recognized that higher rates of metabolism could lead to more rapid detoxification and consequent reduced toxicity).

2) Children may be more sensitive to the toxic effects of pollutants for several reasons. First, children are disproportionately burdened with certain diseases, such as asthma, that might make them more susceptible to the pulmonary effects of indoor air toxics. Second, many organ systems, such as the central nervous system and the reproductive system, continue to develop after birth. Even short-term exposures during critical developmental windows can permanently alter the function of these organ systems.

The prioritization exercise did not take any of the above issues into consideration. Regarding animal studies, few of the studies examined the developing animal. Few if any of the studies on humans involved adolescents, children, infants, or newborns, and their heightened sensitivity and susceptibility, were not addressed. In the discussions of the data and prioritization, there was no discussion or identification of which chemicals the human child would be at greater risk from as compared to the adult.

In keeping with USEPA guidelines, this exercise should take into consideration sensitive populations, which include children, people with diseases such as asthma or chronic obstructive pulmonary disease, pregnant females etc.

Realizing the published animal and the human data are probably not adequate to quantitatively estimate the heightened or reduced sensitivity of children as compared to adults, it would be a useful exercise for the Agency to identify those chemicals from which children may be at greater or lesser risk, and, if possible, determine a relative risk (lesser, slightly greater, moderately greater, very much greater risk) as compared to the adult. One Member noted, however, it was not clear how this goal could be accomplished without the application of considerably greater resources than had been devoted to this effort. This Member suggests that, given such resources:, a feasible option might be to simply highlight those substances for which there are known highly

susceptible groups not covered by the usual safety factors in the derivation of RBCs, or known higher exposures.

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